

Selecting a treatment for primary varicose veins

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The treatment of varicose veins includes injection/compression sclerotherapy and surgical stripping or ligation or both. Surgery appears to be favoured when the saphenous system is involved or when the patient is 35 to 64 years old or presents with ankle edema or flare. On the other hand, sclerotherapy has been found to be more effective in patients with dilated superficial veins or incompetent perforating veins in the lower legs and to be more acceptable and less expensive than surgical treatment.

Les varices sont justiciables soit de la sclérothérapie par injection et compression, soit d'un traitement opératoire (éveinage ou ligature), soit des deux. On préfère opérer lorsque les saphènes sont atteintes, chez les malades âgés de 35 à 64 ans et chez ceux qui présentent au cou-de-pied de l'œdème ou une efflorescence de fines télangiectasies. Mais la sclérothérapie est meilleure dans les varices superficielles et les insuffisances

des veines perforantes au niveau des jambes. Elle est moins chère que l'opération, et les malades s'y prêtent plus volontiers.

Primary varicose veins are very common in Europe and North America; one report places the prevalence as high as 20% and the female:male ratio at 5:1.¹ In these days of escalating health care costs the treatment of varicose veins has emerged as a major expenditure. The cost of surgical treatment in England and Wales in 1975 was in the order of £15 million per annum.² In Quebec the total expenditure for the treatment of varicose veins in 1980 was \$7 million, of which \$5 million was for injection of sclerosants, alone or following surgery (Department of Social Affairs of Quebec: unpublished data, 1980). In this review of the literature we examine the outcomes of existing methods of treatment to help physicians choose the most efficacious method.

Diagnosis

The appropriateness of any treatment depends on the accuracy of the diagnosis. Because our understanding of primary varicose veins is less than complete, diagnosis and treatment are based on manifestations rather than on an adequate knowledge of the causative factors. Since as many as 23% of patients referred for treatment of varicose veins may, in fact, be manifesting symptoms and signs similar but not related to those of the disease, careful clinical examination is mandatory.³

Primary varicose veins are en-

larged, tortuous superficial veins in the legs associated with primary incompetence of venous valves, mainly at the origin of the long saphenous, short saphenous or ankle perforating veins. The main object of the diagnostic process is to exclude secondary varicose veins resulting from deep-vein thrombosis or arteriovenous fistulae.

The numerous diagnostic procedures applicable include Brodie-Trendelenburg's, multiple-tourniquet, Perthes', and compression and percussion tests as well as ultrasonography, venography, thermography and pressure studies.⁴⁻⁶ Of these, Brodie-Trendelenburg's test appears to be the most reliable for detecting uncomplicated varicose veins and valvular incompetence. Ultrasonography may be very helpful when one is screening for deep-vein thrombosis since it is not invasive.⁵ Though Bezzouni⁷ supported the use of ascending venography for all venous disorders, most reports in the current literature recommend a more conservative diagnostic approach, with application of venography only when certain venous disorders are suspected.^{4-6,8,9} With the availability of image intensification and less viscous and toxic contrast media it is possible to determine the site and extent of incompetent perforating channels and accessory veins, ensure the patency of deep veins and demonstrate short saphenous insufficiency.⁶

Only after the diagnostic procedures have been applied and the location and severity of the problem described as precisely as possible should consideration be given to the question of whether to treat it.

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To treat or not to treat?

The literature suggests that at least four factors, in addition to those usually involved in determining the level of surgical risk for the patient, contribute to the decision of whether to treat the patient: pregnancy, obesity, use of oral contraceptives and age.

In a pregnant woman varicose veins may recede after delivery; current practice and the results of research evaluating the outcome of treatment of varicosities during pregnancy support only palliative treatment before delivery,^{5,8,10-14} although some investigators continue to advocate stripping between the 4th and 7th months of gestation^{15,16} or injections.¹⁷⁻²⁰

The literature on the treatment of varicosities in obese individuals reports equivocal results for sclerotherapy. Although obesity makes diagnosis and the application of compression therapy more difficult, Doran and White² demonstrated good results with sclerotherapy in short limbs and fat thighs. Dodd and Cockett,⁵ however, argued in favour of surgery and noted that injection/compression sclerotherapy carries the risk of a severe perivenous reaction that may result in painful fat necrosis.

Deep-vein thrombosis may develop following the use of oral contraceptives during treatment of varicose veins. Stein¹³ had encountered only one such case and therefore saw no reason to stop the use of oral contraceptives during treatment. While the *British Medical Journal*²¹ supported this stand, Orbach¹² and Stother and colleagues²² did not.

The patient's age is another factor to be considered in the treatment decision. Patients over 65 years of age are frequently discouraged from opting for any form of treatment since the risk of complications, the fragility of their skin and their reduced level of activity greatly diminish the chances of a successful outcome. In a significant study Beresford and associates²³ discovered that among individuals aged 35 to 44 and 45 to 64 years the probability of retreatment was significantly less in those who had been treated surgically than in those who had received injection/compression sclerotherapy

($p < 0.05$ for those aged 35 to 44 years and $p < 0.001$ for those aged 45 to 64 years).

Treatment alternatives

The indications for surgery or sclerotherapy are by no means universally agreed upon. Leg pain and ankle edema cannot be attributed to even the most severe case of varicose veins without a careful search for other causes. Some surgery is cosmetic and may be performed at the insistence of the patient. Therefore, evaluation of its effectiveness is based more on the functional and anatomic results in the venous system than on the other signs and symptoms for which the procedure may have been done.

Uncertainty about the cause of primary varicose veins has also handicapped the development and evaluation of treatment. Nevertheless, numerous clinical trials performed since the mid-1960s have attempted to examine the effectiveness of the treatment methods currently in use — injection/compression sclerotherapy and surgical stripping or ligation or both. Another form of treatment combines surgery and sclerotherapy, but, to date, only one trial has formally evaluated its effectiveness.²⁴

Sclerotherapy

Sclerotherapy was rescued from disrepute by Fegan's development of what has become the most frequently used technique.¹⁸ Fegan converted the diseased vein into a fibrous cord by injecting a sclerosant that irritates the intima and produces an inflammatory reaction in the vein wall; subsequent application of compression keeps the vein collapsed until fibrosis is complete. Using this technique Fegan achieved a 70% rate of improvement (or cure) in 1171 patients followed up for 2 to 7 years.

Other evaluative studies of sclerotherapy confirmed Fegan's results. Reid and Rothnie¹¹ used a modification of Fegan's technique to produce diffuse sclerosis with multiple injections at intervals along the diseased vein. They reported a success rate of 90% after 1 year in 1358 cases of varicose veins treated in this fashion.

Dejode¹⁹ obtained an initial success rate of 83%, but the significance of this figure was reduced by a selection bias. In his study the exclusion criteria for subjects receiving sclerotherapy eliminated an important patient population — patients with incompetence of the valves in the long saphenous vein and large varices in the thigh and those with localized groups of "high-tension" varices. Dejode did, however, identify recurrence as a problem following sclerotherapy. Two years after receiving sclerotherapy 20% of his patients required further treatment, and by 4 years 100% had received at least a second course of injections. Stother and colleagues²² reported more favourable results: success rates of 89% and 68%, respectively, 3 months and 3 years after treatment. In more recent studies Dee and Finkelstein²⁵ found that 96% of 200 patients still experienced "symptomatic" relief 5 years after injection/compression sclerotherapy, whereas Douglas and coworkers³ reported that 84% of 538 patients were "normal or improved" 2 years later.

Given the favourable results of these descriptive trials it is not surprising that each author considered sclerotherapy to be comparable to surgical intervention. However, Douglas and coworkers³ acknowledged the appropriateness of surgery in some cases: "We now regard compression-sclerotherapy as an alternative to rather than a replacement for surgical methods".

Although the application of compression, usually for 8 weeks after a course of injections, has generally been regarded as a key component of the success of sclerotherapy, it is no longer uniformly accepted as a necessary part of the treatment. Two randomized clinical trials, one comparing the therapeutic value of 3 and 6 weeks of compression²⁶ and the other comparing the value of 8 hours and 6 weeks of compression,²⁷ demonstrated 6 weeks to be too long. Orbach,¹² in his review of practice patterns, noted that the use of postinjection compression has been omitted in France, apparently without complication. The adoption of a shorter period of compression is attributed to somewhat less concern about poor results in obese patients,

a reduction in complications caused by skin problems, and, most important, a decrease in the amount of inconvenience to the patient, which renders the treatment more acceptable.

Surgical intervention

The surgical management of varicose veins usually consists of ligation of the greater saphenous vein and its tributaries at the saphenofemoral junction, followed by stripping of the long saphenous vein. It frequently also includes ligation of incompetent perforating veins and ligation and stripping of superficial veins.

Whether to ligate and strip the long saphenous vein (i.e., do radical surgery) or to perform multiple ligations only at the detected sites of incompetence in the saphenous vein (i.e., do minor surgery) is a question frequently raised within surgical camps. Lofgren²⁸ argued that "a varicose vein that has been removed cannot recur, but a vein that has been ligated, injected or cauterized has a high likelihood of recanalizing and recurring as a varicosity". One of the more frequent arguments against radical surgery is that it removes veins that might otherwise be used in a bypass operation. Although some surgeons regard a diseased vein as unacceptable for arterial bypass grafting,^{5,28} others continue to recommend caution in the selection of patients for stripping.^{14,25,29,30}

Anesthesia and paresthesia around the ankle and the front of the leg are possible complications of radical surgery. Although not disabling and frequently temporary, such effects are disturbing to the patient and must be considered in any comparison of radical and minor surgery for varicose veins.

Although the initial results of surgery and sclerotherapy appear very similar, advocates of surgery emphasize the long-term effectiveness of an operation and are supported, in part, by a number of studies. Agrifoglio and Edwards³¹ followed up 416 patients at 1 and 14 years and reported good results in 71%, and Haeger³² reported that 92% of 578 patients treated surgically had "satisfactory" outcomes 5 years later. Larson and collaborators,³³ from

the Mayo Clinic, in Rochester, Minnesota, reported a recurrence rate of only 15% in 1000 patients after 10 years, and Rivlin,³⁴ in England, calculated a recurrence rate of 7% in 2000 patients during a 6- to 10-year follow-up period.

In spite of the positive results of these studies, it should be noted that the evaluation of results of surgery for varicose veins can be difficult. In 1976, from a study of patients who underwent surgical treatment with local anesthesia, McAdam and colleagues³⁵ reported agreement rates of up to 98% between observers when they were assessing symptomatic response but rates of up to only 60% when they were evaluating visual changes. Even more disturbing was the finding that intraobserver reliability in the comparison of symptomatic response and visual impression was low, the agreement rate being only 30%. The potential unreliability of outcome measures suggested by these figures presents an interesting problem in the interpretation, comparison and application of study results, whether they relate to surgery or sclerotherapy.

Given the welter of contradictory scientific data, one should be surprised neither by the confusion of the novice nor by the cynicism of the expert. The implementation of randomized clinical trials represents an effort to impose order by comparing treatments within the same trial.

Randomized clinical trials: surgery versus sclerotherapy

To date, at least five randomized clinical trials have been performed to compare the effectiveness of surgical intervention with that of injection/compression sclerotherapy for varicose veins.^{2,23,24,36-38} In four studies surgery and sclerotherapy alone were compared. Beresford and Chant and their associates^{23,36} assessed 100 patients treated with surgical stripping and 115 patients treated with injection/compression sclerotherapy. Hobbs³⁷ treated one group of patients, 170 with stripping and 211 with sclerotherapy, and then another group, 250 with each method. Seddon³⁸ studied 91 patients treated with surgery and 110 treated with sclerotherapy. Doran and White² included 149 patients

treated with surgery and 182 treated with injections. In a fifth study, by Jakobsen,²⁴ the effectiveness of surgery was compared with that of a combination of surgery and sclerotherapy; 161 patients were treated with stripping alone, 157 with sclerotherapy alone and 165 with both procedures. As the gold standard of clinical investigation, the randomized clinical trial applies different treatments to potentially comparable patient groups created through randomization. Consequently, *within* a study the results in each treatment group can be compared with those in the other group, or groups, by a statistical analysis that determines whether the differences in success rates, for example, derive from the treatment or merely from a chance relation. However, the intercomparability of these five randomized clinical trials is very limited because the designs vary in at least two critical areas: the exclusion criteria and the evaluation criteria and process.

The exclusion of a patient from a study is an attempt to eliminate characteristics that could, for example, confound the assessment of outcome or place a patient at higher risk during treatment and thus affect the appropriateness of randomization to one treatment over the other. Within the five studies we reviewed, the criteria were so varied that it appeared that we were attempting to compare different states of disease. When the severity of varicose vein disease was examined as a criterion for exclusion, we found insufficient agreement between the randomized clinical trials; Chant and associates,³⁶ Seddon³⁸ and Jakobsen²⁴ appear to have included patients with ulcers, whereas Doran and White² deliberately excluded them. Furthermore, Chant and associates excluded patients with minimal subcutaneous varices; no such exclusion was evident in the other trials. Other patients who appeared to be excluded included those over 60 years of age³⁶ and those who had previously received treatment.^{24,36} Patients who expressed a preference for one treatment over another were excluded on ethical grounds in only one of the trials.³⁶

Evaluation criteria measuring the success or failure of treatment were

dealt with in a variety of ways. Hobbs³⁷ assessed the outcome objectively or subjectively as "cured, improved or failed" on the basis of the poorest assessment by the surgeon or the patient: cured meant that there were no symptoms or signs and that no varicose veins could be found, and failed meant that "the leg was the same or worse than before". The need for additional treatment (i.e., the treatment had failed) was the measure of outcome used by Beresford and Chant and their associates^{23,36} and by Doran and White;² Seddon³⁸ applied a nonspecific "satisfactory" to indicate success. The most detailed and truly measurable and reproducible assessment criteria were defined by Jakobsen,²⁴ who, like Hobbs,³⁷ elaborated objective and subjective criteria but, unlike Hobbs, integrated both in his evaluation to ascertain physical as well as emotional responses to treatment.

Jakobsen's approach dealt with the problems of observer reliability by providing specific measurable characteristics before and after surgery (Table I) and by using both subjective and objective appraisals. Jakobsen took another step to reduce measurement bias by having an independent observer verify a sample of the follow-up evaluations. Except in the study by Beresford and Chant and their associates,^{23,36} in which an independent observer performed all the follow-up examinations, the author-surgeons alone were responsible for determining outcomes. Hence, the results were vulnerable to the "halo effect" — that is, the therapist who is also the evaluator tends, albeit unconsciously, to bias the evaluation towards

his or her treatment of choice.

In spite of differences in research methods, the results of the five randomized clinical trials we reviewed point toward the same conclusion: *in the long term*, radical surgery, possibly in conjunction with sclerotherapy, is the treatment of choice in most cases. After the first 3 years of their study Chant and associates³⁶ reported no difference between the two methods of treatment. However, 2 years later the stability of the improved clinical outcome after surgery became evident.²³ Furthermore, the later results suggested that two signs, ankle edema and ankle flare, are indications for surgery. (Ankle edema is defined as "a palpable indentation of the skin following firm pressure applied for 10 seconds by the thumb to the lower leg immediately proximal to the medial malleolus" and ankle flare as "a cluster of small, dilated, tortuous, elongated venules, usually found around the region of the medial malleolus, sometimes around the lateral malleolus and occasionally elsewhere on the lower leg or foot".²³) These investigators controlled for age and found that patients with ankle edema or flare were more likely to require further treatment if they had initially undergone injection/compression sclerotherapy.

On the basis of a follow-up period of only 17 to 18 months Seddon³⁸ agreed with the conclusion of Chant and associates³⁶ that the results of sclerotherapy and surgery are essentially the same. Two years later Doran and White² announced that sclerotherapy should be the primary intervention technique, since they found that its short-term effects

were better than those of surgery. Unfortunately, from their data the long-term benefits of sclerotherapy are, at best, uncertain, given the large number of patients lost to follow-up and the limited (2-year) period of the study. Meanwhile, Hobbs,³⁹ in summarizing data on the 6th year of his 10-year follow-up study, calculated that although 82% of his patients who had undergone sclerotherapy were "cured" after 1 year, the proportion had decreased to 7% 6 years later. For the same period the success rate of surgery, which had initially compared unfavourably with compression sclerotherapy, did not demonstrate a similar dramatic decline. In other words, at 6 years the success rate of surgery was 80%, whereas that of compression sclerotherapy was only 35%.

Convinced that one treatment's success over another depends largely on the category of varicose vein it is applied to, Hobbs³⁹ re-examined his results in the context of three classifications. The analysis demonstrated that surgical stripping is most effective when the saphenous system is involved and that injection/compression sclerotherapy is best for dilated superficial veins and incompetent perforating veins in the lower legs. Hobbs therefore concluded that since roughly 60% of patients with varicose veins have incompetence of either the saphenofemoral junction or the saphenopopliteal junction, most patients should be treated surgically.

Jakobsen's well designed randomized clinical trial²⁴ supports a similar conclusion. He found that the results of surgical stripping 3 years after treatment were significantly better ($p < 0.0005$) than those of combined treatment with ligation and compression sclerotherapy and that the results of combined treatment were significantly better ($p < 0.0005$) than those of sclerotherapy alone. Though Jakobsen included only patients with saphenous and perforated varicosities in his study, the replication of Hobbs' results,³⁷ differentiating treatment modalities for types of varicosities, would have been a significant contribution.

Special emphasis should be placed on the studies of Hobbs,³⁹ Beresford and Chant and their associates,^{23,36} and Jakobsen.²⁴ The results unani-

Table I—Evaluation criteria for assessing the results of treatment of varicose veins²⁴

Objective

- A: No visible or palpable varices.
- B: A few visible or palpable varices less than 5 mm in diameter.
- C: Remaining or newly formed varices more than 5 mm in diameter; main trunks and incompetent perforating veins are absent.
- D: Main trunks or incompetent perforating veins, or both, are present.

Subjective

- A: No inconvenience to the patient.
- B: Slight functional or cosmetic imperfection, but satisfaction with the result.
- C: Appreciable functional or cosmetic failure; although there is some improvement, there is dissatisfaction with the result.
- D: Unaltered or greater inconvenience to the patient.

mously demonstrate the efficacy of radical surgery when long-term benefits are considered; moreover, their basic methods were sound and thus less open to criticism.

Patient acceptability and cost of treatment

The impact of two qualifying variables must now be examined for their relation to clinical outcome in support of surgical management of varicose veins. The acceptability of the procedure to the patient and the cost of treatment undeniably affect the treatment decision.

Patient acceptability

In spite of the surgeon's power of persuasion, arguments for the more frequent use of surgery are fruitless if patients reject such an intervention. Patients' reactions to surgery range from satisfaction with the procedure to outright refusal to have anything to do with it. To date, in only two of six studies eliciting the opinions of patients has a preference for radical surgery been found.^{4,40} In the study by Nabatoff⁴ patients underwent both surgery and compression sclerotherapy before deciding that the injections caused more pain and disability than the surgery. In contrast, Munn and associates⁴¹ compared patients' opinions on stripping and ligation and found that, despite a definite improvement in the stripped limbs, the patients rejected stripping because of the associated paresthesia and pain.

In support of compression sclerotherapy as the intervention most acceptable to patients, Dee and Finkelstein²⁵ reported that patients who had received both sclerotherapy and surgery almost unanimously preferred the former. In another study 96 patients were interviewed following compression sclerotherapy: 72% said they preferred sclerotherapy, 8% said they would have preferred surgery, and 20% did not have a preference.⁴² The replies of patients participating in a long-term randomized controlled trial have also been documented: "Of the patients treated surgically, 47 per cent said they would rather have been treated by injection compression; of the patients treated by injection compression,

95 per cent still preferred this type of treatment and would not want surgical treatment if [the varicosities] recurred".⁴³

One factor in a patient's hesitation to choose surgery may be a fear of complications that, though rare, can be serious. Minor complications of sclerotherapy, although more frequent and uncomfortable (e.g., in a series of 663 limbs localized phlebitis developed in 10% and ulcers in 4%⁴⁴), are fortunately self-limiting and thus less threatening.

If complications are put aside, one of the most obvious drawbacks of surgery is the inconvenience to the patient. The length of hospital stay, averaging as much as 8.7 days in one Canadian study,³ and a slower return to normal activities result in a significant loss of working hours and a disruption in the home.^{23,36,41,45}

To avoid or reduce the frequency of such disadvantages more physicians are promoting "short-stay surgery" for varices.^{46,47} Doran and White² stated that "there is no limit to the amount of [varicose vein] surgery" that can be done during a 2-day hospital stay. Complete stripping of varicose veins on an outpatient, ambulatory basis is a more radical approach,⁴⁸ and the use of a local anesthetic for stripping of the long saphenous vein is being tested as a potential "facilitator" in day-care management.⁴⁹ The stripping of varicose veins on an ambulatory basis worries some surgeons because it "would appear to compromise sharply the thoroughness of the operation, which can be very lengthy, even with a team effort".²⁸

Cost of treatment

Comparing the costs of sclerotherapy and surgery clearly indicates that surgery is more expensive. A 1982 Ontario study found that patients receiving sclerotherapy required an average of 3.7 clinical visits, for a total treatment cost of \$154.10; those undergoing surgery were in hospital an average of 8.7 days, for a total average cost of \$1615 (i.e., about 10 times the cost of sclerotherapy).³ Unpublished data from Quebec for 1980 indicate that patients receiving sclerotherapy from general practitioners required an average of 3.05 visits to complete

the treatment, for a total cost to the health care system of \$54; surgical stripping was five times more costly, at \$245.32 per patient, *for physician services alone*.

The 1972 report from Cardiff, Wales, presents the most detailed analysis of the costs incurred in the treatment of varicose veins.⁵⁰ In 1967-68 the average direct and indirect costs per patient for injection/compression sclerotherapy and surgical treatment were estimated to be £9.77 and £44.22 respectively. These figures include the estimated costs to the British National Health Service and to the patient. With respect to costs to the patient alone, injection/compression sclerotherapy required an average of 7.3 clinic appointments per patient, 30 hours of the patient's time and a mean of 6.4 days' absence from work (an average earnings loss of £29) for treatment and convalescence. Surgery required 3.7 days in hospital, 100 hours of the patient's time and 31.4 days' absence from work (an average earnings loss of £118). Even if it is assumed that recurrence of varicosities following sclerotherapy is frequent, these figures suggest that a saving is still possible when sclerotherapy is chosen.

Conclusion

Three treatment options for primary varicose veins are currently available: surgical stripping and ligation, injection/compression sclerotherapy and a combination of the two. The only randomized clinical trial to evaluate all three options over a 3-year period found that surgical stripping was significantly more effective than a combination of ligation and sclerotherapy and that the combination was significantly more effective than sclerotherapy alone.²⁴ In general, the results of other studies agree that surgery seems to be the most effective treatment when the saphenous system is involved and when long-term outcome is assessed. It has also been demonstrated that surgery is preferred for patients 35 to 64 years old and for those presenting with signs of ankle edema and flare. Sclerotherapy, however, appears to be more effective for dilated superficial veins and incompetent perforat-

ing veins in the lower leg; at present, it is also the most acceptable and the least expensive method for the patient.

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